IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE, Plaintiffs, v. MYLAN N.V., MYLAN GMBH, MYLAN INC., and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** *Electronically Filed*

Plaintiffs Sanofi-Aventis U.S. LLC ("Sanofi U.S."), Sanofi-Aventis Deutschland GmbH ("Sanofi GmbH"), and Sanofi Winthrop Industrie ("SWIND") (collectively, "Plaintiffs" or "Sanofi"), by and through their attorneys, for their Complaint against Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. ("Mylan Pharma") (collectively, "Mylan" or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*. arising from Mylan's filing of New Drug Application ("NDA") No. 210605 with the United States Food and Drug Administration ("FDA"), seeking approval to commercially market Mylan's proposed copies of Sanofi's Lantus® and Lantus® SoloSTAR® drug products ("Proposed Products") prior to the expiration of United States Patent Nos. 7,476,652 ("the '652 patent"), 7,713,930 ("the '930 patent"), 7,918,833 ("the '833 patent"), 8,512,297 ("the '297 patent"), 8,556,864 ("the '864 patent"), 8,603,044 ("the '044 patent"), 8,679,069 ("the '069 patent"), 8,992,486 ("the '486 patent"), 9,011,391 ("the '391 patent"),

9,233,211 ("the '211 patent"), 9,408,979 ("the '979 patent"), 9,526,844 ("the '844 patent"), 9,533,105 ("the '105 patent"), 9,561,331 ("the '331 patent"), 9,604,008 ("the '008 patent"), 9,604,009 ("the '009 patent"), 9,610,409 ("the '409 patent"), and 9,623,189 ("the '189 patent"), (collectively, "the patents-in-suit"), which cover Lantus® and/or Lantus® SoloSTAR®.

THE PARTIES

2. Plaintiff Sanofi U.S. is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Plaintiff Sanofi GmbH is a German corporation with its principal place of business located at Industriepark Hoechst, Frankfurt Am Main, Germany D-65926.

4. Plaintiff SWIND is a French corporation with its principal place of business located at 20 Avenue Raymond Aron, 92160 Antony, France.

5. On information and belief, Defendant Mylan N.V. is a company organized and existing under the laws of the Netherlands, with its global headquarters and principal offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. On information and belief, Mylan N.V. is in the business of, among other things, marketing and selling follow-on versions of branded pharmaceutical products for the United States market, alone and/or through its subsidiaries, agents, and affiliates. On information and belief, Mylan N.V. is the ultimate corporate parent of Mylan GmbH, Mylan Inc., and Mylan Pharma.

6. On information and belief, Mylan N.V. conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

7. On information and belief, Defendant Mylan GmbH is a company organized and existing under the laws of Switzerland, with a principal place of business at Thurgauerstrasse 40, CH-8050 Zurich, Switzerland. On information and belief, Mylan GmbH is in the business of,

among other things, marketing and selling follow-on versions of branded pharmaceutical products for the United States market, alone and/or through its subsidiaries, agents, and affiliates. On information and belief, Mylan GmbH is a wholly-owned subsidiary of Mylan N.V., is controlled by Mylan N.V., and is an agent and/or affiliate of Mylan Pharma and Mylan Inc.

8. On information and belief, Mylan GmbH conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

9. On information and belief, Defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, among other things, marketing and selling follow-on versions of branded pharmaceutical products for the United States market, alone and/or through its subsidiaries, agents, and affiliates. Mylan Inc. is a wholly-owned subsidiary of Mylan N.V., is controlled by Mylan N.V., and is an agent and/or affiliate of Mylan GmbH and Mylan Pharma.

10. On information and belief, Mylan Inc. conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

11. On information and belief, Defendant Mylan Pharma is a company organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505-4310. On information and belief, Mylan Pharma is in the business of manufacturing and selling follow-on versions of branded pharmaceutical products for the United States market alone and/or through its subsidiaries, agents, and affiliates. On information and belief, Mylan Pharma is wholly-owned subsidiary of Mylan Inc., is controlled by Mylan Inc., and is an agent and/or affiliate of Mylan GmbH.

12. On information and belief, Mylan Pharma conducts business operations, directly or through its subsidiaries, agents and/or affiliates, in the State of New Jersey.

13. On information and belief, Mylan N.V. and Mylan GmbH operate in the United States and in the State of New Jersey through Mylan Inc. and Mylan Pharma. On information and belief, Mylan Inc. and Mylan Pharma are United States agents for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with the Food and Drug Administration ("FDA").

14. For example, on information and belief, at least Mylan Inc. and Mylan GmbH worked in concert to prepare and file NDA No. 210605 by conducting a "Non-inferiority Study to Compare the Efficacy and Safety of Mylan's Insulin Glargine With Lantus® in Type 2 Diabetes Mellitus Patients" and a "Non-inferiority Study to Compare the Efficacy and Safety of Mylan's Insulin Glargine With Lantus® in Type 1 Diabetes Mellitus Patients." *See* Exhibits S and T. Mylan Inc. is listed as the Sponsor and Responsible Party on these studies and Mylan GmbH is listed as Collaborator. *Id.*

15. On June 5, 2017, Mylan Pharma filed petitions for *Inter Partes* Review of the '652 and '930 patents. *Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2017-01526, Paper 2 (P.T.A.B. June 5, 2017); *Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2017-01528, Paper 2 (P.T.A.B. June 5, 2017). In accordance with 37 C.F.R. § 42.8(b)(1), Mylan identified Mylan Pharma, Mylan Inc., Mylan GmbH, and Mylan N.V., among others, as real parties-in-interest. *Id.* at 2.

16. That Mylan Pharma, Mylan Inc., Mylan GmbH, and Mylan N.V. are real parties-in-interest to the petitions filed in IPR2017-01526 and IPR2017-01528 indicates that all four Mylan entities stand to benefit from approval of NDA No. 210605.

17. On information and belief, the acts of Mylan GmbH complained of herein were done at the direction and/or, with the authorization of, and/or with the cooperation, participation, and assistance of Mylan N.V., Mylan Inc., and Mylan Pharma.

18. On information and belief, Mylan Inc. is the registrant organization for the website mylan.com. *See* Exhibit U. Mylan Inc. has used Mylan Pharma's address as the registrant address for the website mylan.com, further indicating that Defendants operate as one entity. *See id.*

19. On information and belief, Mylan holds itself out as having contacts with the State of New Jersey by stating on its website that it aims to provide a "Better Health for a Better New Jersey." *See* Exhibit V. Specifically, the website reports that in "[i]n 2016, Mylan generics saved New Jersey $700 million." *Id.* Further, it states that "Mylan is the leader in the fight against many of New Jersey's most prevalent diseases." *Id.*

20. On information and belief, Mylan holds itself out as having contacts with the State of New Jersey by stating in its website that:

> Mylan's commitment to expanding access to medicine extends beyond just offering products. Take potentially life-threatening allergic reactions, or anaphylaxis. These reactions can occur quickly and without warning. Of the nearly 8.9 million people in New Jersey, approximately 178,000 may be at risk.

Exhibit W.

21. On information and belief, Mylan holds itself out as having contacts with the State of New Jersey by stating in its website that:

> Over the past five years, 54,424 free epinephrine auto-injectors have been provided to 3,577 schools in New Jersey, approximately 81% of the state's schools. Since the program began in 2012, epinephrine auto-injectors provided through the EpiPen4Schools program have been used 109 times in New Jersey to treat an anaphylactic reaction in the school setting.

Id. at 2.

22. On information and belief, Mylan GmbH, Mylan N.V., Mylan Inc., and Mylan Pharma hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

JURISDICTION AND VENUE

23. Plaintiffs repeat and re-allege paragraphs 1-22 above as if fully set forth herein.

24. This is an action for patent infringement and arises under the patent laws of the United States, Title 35, United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

25. On information and belief, Mylan GmbH, with the assistance and/or direction of Mylan N.V., Mylan Inc., and/or Mylan Pharma, develops, formulates, manufactures, imports, offers for sale, sells, commercializes, markets, and/or distributes follow-on versions of branded pharmaceutical products in/into the United States, including in/into the State of New Jersey.

26. As part of the foregoing act of infringement, Defendant Mylan GmbH transmitted a Notice of Certification ("Notice Letter") pursuant to 21 U.S.C. § 355(b)(3) and 21 C.F.R. § 314.52 regarding NDA No. 210605 to, *inter alia*, Sanofi U.S. located in New Jersey.

27. On information and belief, Mylan, N.V., Mylan Inc., and Mylan Pharma acted in concert with Mylan GmbH to develop Mylan GmbH's copies of Sanofi's Lantus® and Lantus® SoloSTAR® drug products ("Proposed Products").

28. On information and belief, Mylan GmbH, acting in concert with Mylan N.V., Mylan Inc., and Mylan Pharma, prepared and filed NDA No. 210605, seeking approval from the FDA to sell its Proposed Products throughout the United States, including within the State of New Jersey.

29. On information and belief, Mylan, N.V., Mylan Inc., and Mylan Pharma, acting in concert with Mylan GmbH, participated in the preparation and/or filing of NDA No. 210605,

seeking approval from the FDA to sell the Proposed Products throughout the United States, including within the State of New Jersey.

30. Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharma therefore committed an act of infringement in New Jersey, by participating in the preparation, filing, and submission of New Drug Application ("NDA") No. 210605 pursuant to § 505(b)(2) of the FFDCA to FDA, accompanied by a Paragraph IV Certification.

31. This Court has personal jurisdiction over Defendants because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of NDA No. 210605, Defendants intend to and will work in concert to make, use, import, sell, and/or offer for sale the Proposed Products that are the subject of NDA No. 210605 in/into the United States, including in/into the State of New Jersey, prior to the expiration of the patents-in-suit.

32. This Court has personal jurisdiction over Defendants because Defendants maintain continuous and systematic contacts with this judicial district. Either directly, or through their subsidiaries, agents, and/or affiliates, Defendants have conducted and continue to conduct business in this judicial district, including, upon information and belief, by manufacturing, marketing, and selling drug products throughout the United States and in the State of New Jersey.

33. This Court has personal jurisdiction over Mylan N.V. because, *inter alia*, Mylan N.V., on information and belief, directly or through its subsidiaries, agents and/or affiliates: (1) maintains substantial, systemic, and continuous contacts with the State of New Jersey; (2)

regularly transacts and/or solicits business in the State of New Jersey; (3) continuously and systematically places its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States; (4) engages in the regular conduct of business within this judicial district; (5) derives substantial revenue and income from sales of its follow-on versions of branded pharmaceutical products throughout the United States, including in the State of New Jersey; (6) maintains a broad distributorship network within this State; and (7) intends to manufacture for distribution, market, sell, or distribute the Proposed Products to residents of this State, which is confirmed by the filing of NDA No. 210605. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 759-63 (Fed. Cir. 2016), *petition for cert. denied*, *Mylan Pharms. Inc. v. Acorda Therapeutics, Inc.*, No. 16-360 (U.S. Jan. 9, 2017).

34. This Court has personal jurisdiction over Mylan GmbH because, *inter alia*, Mylan GmbH, on information and belief, directly or through its subsidiaries, agents and/or affiliates: (1) maintains substantial, systemic, and continuous contacts with the State of New Jersey; (2) regularly transacts and/or solicits business in the State of New Jersey; (3) continuously and systematically places its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States; (4) engages in the regular conduct of business within this judicial district; (5) derives substantial revenue and income from sales of its follow-on versions of branded pharmaceutical products throughout the United States, including in the State of New Jersey; (6) maintains a broad distributorship network within this State; and (7) intends to manufacture for distribution, market, sell, or distribute the Proposed Products to residents of this State, which is confirmed by the filing of NDA No. 210605. *See Acorda*, 817 F.3d at 759-63.

35. This Court has personal jurisdiction over Mylan Inc. because, *inter alia*, Mylan Inc., on information and belief, directly or through its subsidiaries, agents and/or affiliates: (1) is registered to do business in New Jersey under entity ID No. 0100971292 and has appointed Corporation Service Company, Princeton South Corporate Ctr., Suite 160, 100 Charles Ewing Blvd., Ewing, NJ 08628, as its registered agent for receipt of process; (2) maintains substantial, systemic, and continuous contacts with the State of New Jersey; (3) regularly transacts and/or solicits business in the State of New Jersey; (4) continuously and systematically places its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States; (5) engages in the regular conduct of business within this judicial district; (6) derives substantial revenue and income from sales of its follow-on versions of branded pharmaceutical products throughout the United States, including in the State of New Jersey; (7) maintains a broad distributorship network within this State; and (8) intends to manufacture for distribution, market, sell, or distribute the Proposed Products to residents of this State, which is confirmed by the filing of NDA No. 210605. *See Acorda*, 817 F.3d at 759-63.

36. Additionally, personal jurisdiction over Mylan Inc. is also proper because Mylan Inc. has previously availed itself of the benefits and protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See*, *e.g.*, *Horizon Pharma, Inc. et al. v. Mylan Pharms. Inc. & Mylan Inc.*, Civil Action No. 3-15-cv-03327-MLC-DEA (D.N.J. May 13, 2015); *AstraZeneca Pharms. LP et al. v. Mylan Pharms. Inc. & Mylan Inc.*, Civil Action No. 1-15-cv-07009-RMB-KMW (D.N.J. Sept. 21, 2015).

37. This Court has personal jurisdiction over Mylan Pharma because, on information and belief, directly or through its subsidiaries, agents and/or affiliates, *inter alia*, Mylan Pharma (1) is registered to do business in New Jersey under entity ID No. 0100214277; (2) is registered

as a drug manufacturer and wholesale drug distributer under registration number 5003762; (3) has appointed Corporation Service Company, Princeton South Corporate Ctr., Suite 160, 100 Charles Ewing Blvd., Ewing, NJ 08628, as its registered agent for receipt of process; (4) maintains substantial, systemic, and continuous contacts with the State of New Jersey; (5) regularly transacts and/or solicits business in the State of New Jersey; (6) continuously and systematically places its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States; (7) engages in the regular conduct of business within this judicial district; (8) derives substantial revenue and income from sales of its follow-on versions of branded pharmaceutical products throughout the United States, including in the State of New Jersey; (9) maintains a broad distributorship network within this State; and (10) intends to manufacture for distribution, market, sell, or distribute the Proposed Products to residents of this State, which is confirmed by the filing of NDA No. 210605. *See Acorda*, 817 F.3d at 759-63.

38. Additionally, personal jurisdiction over Mylan Pharma is also proper because Mylan Pharma has previously availed itself of the benefits and protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See*, *e.g.*, *Horizon Pharma, Inc. et al. v. Mylan Pharms. Inc. & Mylan Inc.*, Civil Action No. 3-15-cv-03327-MLC-DEA (D.N.J. May 13, 2015); *AstraZeneca Pharms. LP et al. v. Mylan Pharms. Inc. & Mylan Inc.*, Civil Action No. 1-15-cv-07009-RMB-KMW (D.N.J. Sept. 21, 2015).

39. This Court therefore has personal jurisdiction over all Defendants.

40. Venue is proper in this judicial district as to all Defendants pursuant to 28 U.S.C. §§ 1391 and 1400(b).

41. Venue is proper as to alien defendant Mylan N.V. under § 1391(c)(3).

42. Venue is proper as to alien defendant Mylan GmbH under § 1391(c)(3).

43. Venue is proper as to Mylan Inc. because Mylan Inc. has committed acts of infringement within the district and has a regular and established place of business located in the State of New Jersey through at least its subsidiary, Mylan Specialty, located at 110 Allen Road, 4th Floor, Basking Ridge, NJ 07920 ("Basking Ridge Location"). *See* Exhibits X and Y; *see also* Exhibits Z, AA, and BB (each addressing Mylan's acquisition of Meda, another New Jersey-based Mylan entity).

44. On information and belief, Mylan Inc. committed acts of infringement in New Jersey, and throughout the United States, because it intends to manufacture for distribution, market, sell, or distribute the Proposed Products to residents in the State of New Jersey, which is confirmed by the filing of NDA No. 210605. *See Acorda*, 817 F.3d at 759-63; *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. CV 17-379-LPS, 2017 WL 3980155, at *8-14 (D. Del. Sept. 11, 2017).

45. On information and belief, Mylan Inc. has regular and established places of business located in the State of New Jersey. For example, the Mylan Specialty Basking Ridge Location is both "regular" and "established" as a place business because it maintains a permanent and orderly presence within the State of New Jersey. On information and belief, the Basking Ridge Location functions as Mylan Specialty's corporate offices, *see* Exhibit CC, and Mylan Specialty is registered with the New Jersey Department of Health, and holds a manufacturer and wholesale license issued by the State of New Jersey. *See* Exhibit DD.

46. The Basking Ridge Location is further both "regular" and "established" as a place of business because Mylan regularly markets its prescription drug products from the Basking Ridge facility. For example, HOOVERS reports:

> When a peanut or a bee threatens your very existence, Mylan Specialty (formerly Dey Pharma) is ready to save the day. Its specialty prescription drugs treat severe allergic reactions, respiratory diseases, and psychiatric disorders. It markets EpiPen autoinjectors used by patients to self-administer epinephrine in case of allergic emergencies (anaphylaxis). Its premeasured unit-dose inhalation products include bronchodialators use to treat asthma and chronic obstructive pulmonary disease (COPD). Brands include the EasiVent and Perforomist breathing devices. ***A subsidiary of generic giant Mylan***, Mylan Specialty also offers non-branded generic nebulizer treatment and the Emsam transdermal antidepressant patch.

Exhibit X at 2 (emphasis added).

47. Mylan Specialty's sales activity further demonstrates Mylan's permanent and orderly presence within the State of New Jersey. For example, HOOVERS reports:

> Operations: The EpiPen is Mylan Specialty's top-selling product, accounting for more than half of sales and is the most prescribed treatment for severe allergic reactions in the US. The epinephrine auto-injector is a matter of life and death for some, and commands more than 95% of the US market share. Meridian Medical Technologies manufactures the EpiPen for the company. Mylan Specialty's facilities manufacture nebulized products including Perforomist, DuoNeb, AccuNeb, and generic albuterol. Perforomist, used in the treatment of COPD, chronic bronchitis, and emphysema is another top seller for the company. Mylan Specialty uses existing respiratory treatments to develop its patented products using its drug delivery technologies.

Id. at 3.

48. On information and belief, the Basking Ridge Location is a regular and established place of business for Defendant Mylan Inc. and can be attributed to Defendant Mylan Inc. because Mylan Inc. holds itself out as "ONE Mylan" with Mylan Specialty and other Mylan entities. That is, Mylan Inc. describes itself as "ONE Mylan," with a "horizontally and vertically integrated platform with global scale." Exhibit Z at 4.

49. The Basking Ridge Location can also be attributed to Mylan Inc. because Mylan Inc. owns Mylan Specialty and exercises attributes of possession or control over the Basking Ridge Location. For example, on information and belief, Mylan Inc. pays the salaries and benefits of individuals employed out of the Basking Ridge Location. *See* Exhibit EE.

50. Mylan Inc. and the other Mylan Defendants have a regular and established place of business in this District because they operate as "ONE Mylan" with Mylan Specialty and other Mylan subsidiaries in New Jersey. On information and belief, Mylan Specialty was formerly known as Dey Pharma until 2012 when Mylan changed the name "as part of its efforts to align operations under the Mylan brand." Exhibit X at 3. Specifically, Defendants' CEO, Heather Bresch stated in a press release that:

> The name change to Mylan Specialty is an important milestone and a natural step in our company's evolution. ***Bringing Dey under the Mylan brand will align our specialty business even more directly with everything Mylan stands for*** – innovating to satisfy unmet needs, making reliability and service a habit, doing what's right, not what's easy, and impacting the future through passionate leadership. ***Further, operating under one brand will allow us to speak with a more unified and powerful voice*** as we pursue our mission of providing the world's 7 billion people access to high quality medicine.

Exhibit CC (emphases added). On information and belief, "ONE Mylan" uses one newsroom for press releases such as this, and for press releases involving products from various subsidiaries, including Mylan Specialty. *See* Exhibits FF, GG, HH and II.

51. Mylan Inc. and the other Mylan Defendants have a regular and established place of business in this District because they operate as "ONE Mylan" with Mylan Specialty and other Mylan subsidiaries in the State of New Jersey, as evidenced by shared revenue reporting. On information and belief, Mylan Specialty's revenue is reported with Mylan Inc.'s revenue in the North American segment. In its presentation to investors in 2017, Mylan stated that it has changed its "segment reporting to reflect ONE Mylan." Exhibit JJ at 18. Thus, instead of reporting profitability for two segments—Generic and Specialty—it now reports profitability based on three regional segments—North America, Europe, and the rest of the world. *See id.*

52. Mylan Inc., Mylan Pharma, and the other Mylan Defendants have a regular and established place of business in this District because they operate as "ONE Mylan" with Mylan

Specialty and other Mylan subsidiaries in New Jersey, demonstrated by the Mylan entities' request that they be treated as one cohesive business. For example, in a March 3, 2017 comment in response to an FDA notice and request for information to assess Generic Drug User Fee Amendments ("GDUFA") program fees for fiscal year 2018, Mylan Pharma requested that the "'affiliated' corporate entities listed below be consolidated under 'Mylan Inc.' for the purposes of assessing a single GDUFA II program fee[.]" Exhibit KK. The corporate entities listed included both Mylan Pharma and Mylan Specialty. *See id.*

53. Mylan Inc., Mylan Pharma, and the other Mylan Defendants have a regular and established place of business in this District because they operate as "ONE Mylan" with Mylan Specialty in the State of New Jersey, in part because the Mylan Defendants post job openings for the Basking Ridge Location on its website. *See* Exhibit LL.

54. The Mylan Defendants have a regular and established place of business in this District because they operate as "ONE Mylan," and several Mylan entities, including Mylan Inc., regularly run clinical trials in locations throughout the State of New Jersey, including at brick and mortar locations in, for example, Lawrenceville and Plainsboro. *See* Exhibit MM. At least one Mylan clinical trial uses a Somerset-based hotline. *See* Exhibit NN.

55. Venue is proper as to Mylan Pharma because Mylan Pharma has committed acts of infringement within the district and has a regular and established place of business located in the State of New Jersey through at least its affiliate, Mylan Specialty, located at the Basking Ridge Location.

56. On information and belief, Mylan Inc. is a corporate parent of both Mylan Pharma and Mylan Specialty.

57. On information and belief, Mylan Pharma has committed acts of infringement in the State of New Jersey, and throughout the United States, because it intends to manufacture for distribution, market, sell, or distribute the Proposed Products to residents of this State, which is confirmed by the filing of NDA No. 210605. *See Acorda*, 817 F.3d at 759-63; *BMS*, 2017 WL 3980155, at *8-14.

58. On information and belief, the Basking Ridge Location is both "regular" and "established" as a place business for at least the reasons set out in ¶¶ 45-54.

59. On information and belief, the Basking Ridge Location is a place of business for Defendant Mylan Pharma because Mylan Inc. and Mylan Pharma operate as one entity, and exercise possession and/or control over the Basking Ridge location by, including, but not limited to, holding themselves out as "ONE Mylan" with Mylan Specialty and other Mylan entities. The Basking Ridge location is part of "ONE Mylan."

60. On information and belief, the Basking Ridge Location is a place of business for Mylan Pharma because Mylan Inc. and Mylan Pharma operate as one entity, and Mylan Inc. operates through the Basking Ridge Location. Though Mylan Inc. is incorporated in Pennsylvania, it corresponds with the FDA using Mylan Pharma's West Virginia address. *See* Exhibits OO and PP. For example, the FDA sent a letter to Mylan Inc. regarding its petition requesting the FDA to stay the approval of a drug, and addressed the letter to "Brian S. Roman, Vice President and General Counsel, North America, Mylan, Inc., 781 Chestnut Ridge Road, Morgantown, WV 26505." Exhibit PP.

61. On information and belief, the Basking Ridge Location is a place of business for Mylan Pharma because Mylan Inc. and Mylan Pharma operate as one entity, and the Basking Ridge Location has been "aligned … under the Mylan brand." Exhibit X at 3 ("In 2012 Mylan

changed the company's name from Dey Pharma to Mylan Specialty as part of its efforts to align operations under the Mylan brand."). Specifically, Mylan CEO, Heather Bresch stated in a press release that:

> The name change to Mylan Specialty is an important milestone and a natural step in our company's evolution. ***Bringing Dey under the Mylan brand will align our specialty business even more directly with everything Mylan stands for*** – innovating to satisfy unmet needs, making reliability and service a habit, doing what's right, not what's easy, and impacting the future through passionate leadership. ***Further, operating under one brand will allow us to speak with a more unified and powerful voice*** as we pursue our mission of providing the world's 7 billion people access to high quality medicine.

Exhibit CC (emphases added).

62. On information and belief, the Basking Ridge Location is a place of business for Mylan Pharma because Mylan Specialty, Mylan Inc., and Mylan Pharma's revenue is reported together as part of one North American segment. For instance, in its presentation to investors in 2017, Mylan stated that it has changed its "segment reporting to reflect ONE Mylan." Exhibit JJ at 18. Thus, instead of reporting profitability for two segments—Generic and Specialty—it now reports profitability based on three regional segments—North America, Europe, and the rest of the world. *See id.*

63. On information and belief, the Basking Ridge Location is a place of business for Mylan Pharma because Mylan Inc., Mylan Pharma, and Mylan Specialty all operate as one entity. For example, in a March 3, 2017 comment in response to an FDA notice and request for information to assess GDUFA program fees for fiscal year 2018, Mylan Pharma requested that the "'affiliated' corporate entities listed below be consolidated under 'Mylan Inc.' for the purposes of assessing a single GDUFA II program fee[.]" Exhibit KK. The corporate entities listed included Mylan Pharma and Mylan Specialty. *See id.*

64. On information and belief, the Basking Ridge Location is a place of business for Mylan Pharma because Mylan Inc., Mylan Pharma, and Mylan Specialty all operate as one entity. As noted above, Mylan posts job openings for the Basking Ridge Location on its website. *See* Exhibit LL.

65. Venue is proper as to all Defendants.

THE PATENTS-IN-SUIT

66. On January 13, 2009, the '652 patent, entitled "Acidic Insulin Preparations Having Improved Stability," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). A true and correct copy of the '652 patent is attached as Exhibit A to this Complaint.

67. On May 11, 2010, the '930 patent, entitled "Acidic Insulin Preparations Having Improved Stability," was duly and legally issued by the PTO. A true and correct copy of the '930 patent is attached as Exhibit B to this Complaint.

68. On April 5, 2011, the '833 patent, entitled "Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '833 patent is attached as Exhibit C to this Complaint.

69. On August 20, 2013, the '297 patent, entitled "Pen-Type Injector," was duly and legally issued by the PTO. A true and correct copy of the '297 patent is attached as Exhibit D to this Complaint.

70. On October 15, 2013, the '864 patent, entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices," was duly and legally issued by the PTO. A true and correct copy of the '864 patent is attached as Exhibit E to this Complaint.

71. On December 10, 2013, the ’044 patent, entitled “Pen-Type Injector,” was duly and legally issued by the PTO. A true and correct copy of the ’044 patent is attached as Exhibit F to this Complaint.

72. On March 25, 2014, the ’069 patent, entitled “Pen-Type Injector,” was duly and legally issued by the PTO. A true and correct copy of the ’069 patent is attached as Exhibit G to this Complaint.

73. On March 31, 2015, the ’486 patent, entitled “Pen-Type Injector,” was duly and legally issued by the PTO. A true and correct copy of the ’486 patent is attached as Exhibit H to this Complaint.

74. On April 21, 2015, the ’391 patent, entitled “Pen-Type Injector,” was duly and legally issued by the PTO. A true and correct copy of the ’391 patent is attached as Exhibit I to this Complaint.

75. On January 12, 2016, the ’211 patent, entitled “Relating to a Pen-Type Injector,” was duly and legally issued by the PTO. A true and correct copy of the ’211 patent is attached as Exhibit J to this Complaint.

76. On August 9, 2016, the ’979 patent, entitled “Pen-Type Injector,” was duly and legally issued by the PTO. A true and correct copy of the ’979 patent is attached as Exhibit K to this Complaint.

77. On December 27, 2016, the ’844 patent, entitled “Pen-Type Injector,” was duly and legally issued by the PTO. A true and correct copy of the ’844 patent is attached as Exhibit L to this Complaint.

78. On January 3, 2017, the ’105 patent, entitled “Drive Mechanisms Suitable for Use in Drug Delivery Devices,” was duly and legally issued by the PTO. A true and correct copy of the ’105 patent is attached as Exhibit M to this Complaint.

79. On February 7, 2017, the ’331 patent, entitled “Drive Mechanisms Suitable for Use in Drug Delivery Devices,” was duly and legally issued by the PTO. A true and correct copy of the ’331 patent is attached as Exhibit N to this Complaint.

80. On March 28, 2017, the ’008 patent, entitled “Drive Mechanisms Suitable for Use in Drug Delivery Devices,” was duly and legally issued by the PTO. A true and correct copy of the ’008 patent is attached as Exhibit O to this Complaint.

81. On March 28, 2017, the ’009 patent, entitled “Drive Mechanisms Suitable for Use in Drug Delivery Devices,” was duly and legally issued by the PTO. A true and correct copy of the ’009 patent is attached as Exhibit P to this Complaint.

82. On April 4, 2017, the ’409 patent, entitled “Drive Mechanisms Suitable for Use in Drug Delivery Devices,” was duly and legally issued by the PTO. A true and correct copy of the ’409 patent is attached as Exhibit Q to this Complaint.

83. On April 18, 2017, the ’189 patent, entitled “Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices,” was duly and legally issued by the PTO. A true and correct copy of the ’189 patent is attached as Exhibit R to this Complaint.

84. The ’652, ’930, ’833, ’297, ’864, ’044, ’069, ’486, ’391, ’211, ’979, ’844, ’105, ’331, ’008, ’009, ’409, and ’189 patents are collectively referred to herein as “the patents-in-suit,” and true and correct copies each patent are attached respectively as Exhibits A-R. By assignment, Sanofi GmbH owns all right, title, and interest in and to the patents-in-suit. Sanofi

U.S. and/or SWIND are the exclusive licensees of certain rights in or to the patents-in-suit. Plaintiffs have the right to sue and recover damages for the infringement of the patents-in-suit.

LANTUS® AND LANTUS® SOLOSTAR®

85. Sanofi U.S. is the holder of approved New Drug Application ("NDA") No. 21-081 for insulin glargine [rDNA origin] for injection, which is prescribed and sold in the United States under the trademarks Lantus® and Lantus® SoloSTAR®. Currently, there is one follow-on version of Lantus® SoloSTAR® on the market in the United States, manufactured and distributed by Eli Lilly and Company under a license from Plaintiffs. There are no non-licensed generic or follow-on versions of Lantus® or Lantus® SoloSTAR® on the market in the United States.

86. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by FDA under the FFDCA. The patents-in-suit are listed in the Orange Book as covering Sanofi's Lantus® and/or Lantus® SoloSTAR® products.

87. Each of the patents-in-suit was submitted for listing and was listed in the Orange Book for Sanofi's NDA No. 21-081 prior to Mylan's submission of NDA No. 210605.

ACTS GIVING RISE TO THIS ACTION

88. On information and belief, and as stated in the letter dated September 15, 2017, and received by Plaintiffs on or about September 18, 2017 (purporting to be a notice pursuant to Section 505(b)(2)(A)(iv), (b)(3) of the FFDCA (the "Notice Letter")), Mylan GmbH submitted NDA No. 210605 to the FDA pursuant to 21 U.S.C. § 355(b)(2) seeking FDA's approval to engage in the commercial manufacture, use, sale and/or importation of its versions of Lantus® and Lantus® SoloSTAR®, an insulin glargine [rDNA origin] 100 u/mL for subcutaneous injection including a vial containing the active ingredient insulin glargine in 100 u/mL ("Proposed Vial Product") and a prefilled pen containing the active ingredient insulin glargine in

300 units/3 mL (100 units/mL) ("Proposed Prefilled Pen Product") (collectively, "Proposed Products"). On information and belief, Mylan's NDA No. 210605 contains data from bioavailability and/or bioequivalence studies conducted in connection with Sanofi U.S.'s NDA No. 21-081. The filing of Mylan's NDA No. 210605 constitutes an act of infringement under 35 U.S.C. § 271(e)(2)(A).

89. On information and belief, Mylan GmbH, in collaboration with Mylan N.V., Mylan Inc., and Mylan Pharma, submitted NDA No. 210605 to the FDA under 21 U.S.C. § 355(b)(2) of the FFDCA containing data from bioavailability or bioequivalence studies conducted in connection with Sanofi U.S.'s NDA No. 21-081 and seeking the FDA's approval to manufacture commercially and sell its Proposed Products.

90. Upon information and belief, Mylan GmbH, in concert with Mylan N.V., Mylan Inc., and Mylan Pharma, collaborated in the development of Mylan's Proposed Products and preparation and filing of NDA No. 210605.

91. On information and belief, on September 15, 2017, as part of the foregoing act of infringement, Mylan GmbH, in collaboration with Mylan N.V., Mylan Inc., and Mylan Pharma, sent a Notice of Certification (the "Notice Letter") pursuant to 21 U.S.C. § 355(b)(2) and 21 C.F.R. § 314.52 to Sanofi U.S. and Sanofi GmbH, which discloses that Mylan's NDA No. 210605 contained Paragraph IV certifications for the patents-in-suit. In its Notice Letter, Mylan stated that its certifications to the FDA allege that the patents-in-suit are not valid, are unenforceable, and/or will not be infringed by the manufacture, use, offer to sell, sale, or importation of the Proposed Products before their respective expirations.

92. Sanofi U.S. received Mylan's Notice Letter on September 18, 2017 in the District of New Jersey.

93. Sanofi GmbH received Mylan's Notice Letter on September 18, 2017 in Germany.

94. Mylan's Notice Letter was accompanied by an Offer of Confidential Access ("OCA").

95. Since receiving Mylan's Notice Letter and the accompanying OCA, Sanofi has negotiated in good faith with Mylan to procure a copy of NDA No. 210605 and related product information under restrictions as would apply had a protective order been issued. Sanofi timely responded to all correspondence with Mylan and sought to reach reasonable compromise with Mylan regarding its OCA. These negotiations have been unsuccessful.

96. Because of the onerous and unreasonable restrictions on production, disclosure, and use of the information under the OCA insisted upon by Mylan, which Sanofi could not reasonably accept, no information under the OCA has been supplied by Mylan to Sanofi.

97. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that the Proposed Products fall within the scope of one or more claims of the patents-in-suit.

98. Plaintiffs commenced this action within 45 days after receiving Mylan's Notice Letter.

99. FDA's approval of Mylan's NDA No. 210605 may only be made effective upon a date consistent with 21 U.S.C. § 355(c)(3)(C).

100. On information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of its Proposed Products would infringe one or more claims of each of the patents-in-suit, directly or indirectly.

COUNT 1

(Infringement of U.S. Patent No. 7,476,652)

101. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

102. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Products before the expiration of the '652 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Products using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '652 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '652 patent under 35 U.S.C. § 271(e)(2)(A).

103. On information and belief, Mylan was aware of the '652 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Products would infringe the '652 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Products constitute a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Products will constitute infringement.

104. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the

expiration of the '652 patent, or any later date of exclusivity to which Plaintiffs and/or the '652 patent are, or become, entitled.

COUNT 2

(Infringement of U.S. Patent No. 7,713,930)

105. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

106. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Products before the expiration of the '930 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Products using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '930 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '930 patent under 35 U.S.C. § 271(e)(2)(A).

107. On information and belief, Mylan was aware of the '930 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Products would infringe the '930 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Products constitute a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Products will constitute infringement.

108. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm

continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '930 patent, or any later date of exclusivity to which Plaintiffs and/or the '930 patent are, or become, entitled.

COUNT 3

(Infringement of U.S. Patent 7,918,833)

109. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

110. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '833 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '833 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '833 patent under 35 U.S.C. § 271(e)(2)(A).

111. On information and belief, Mylan was aware of the '833 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '833 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

112. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '833 patent, or any later date of exclusivity to which Plaintiffs and/or the '833 patent are, or become, entitled.

COUNT 4

(Infringement of U.S. Patent 8,512,297)

113. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

114. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '297 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '297 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '297 patent under 35 U.S.C. § 271(e)(2)(A).

115. On information and belief, Mylan was aware of the '297 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '297 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its

manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

116. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '297 patent, or any later date of exclusivity to which Plaintiffs and/or the '297 patent are, or become, entitled.

COUNT 5

(Infringement of U.S. Patent 8,556,864)

117. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

118. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '864 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '864 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '864 patent under 35 U.S.C. § 271(e)(2)(A).

119. On information and belief, Mylan was aware of the '864 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '864 patent under 35 U.S.C. §§ 271(a), (b), and/or (c),

literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

120. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '864 patent, or any later date of exclusivity to which Plaintiffs and/or the '864 patent are, or become, entitled.

COUNT 6

(Infringement of U.S. Patent 8,603,044)

121. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

122. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '044 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '044 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '044 patent under 35 U.S.C. § 271(e)(2)(A).

123. On information and belief, Mylan was aware of the '044 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale

and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '044 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

124. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '044 patent, or any later date of exclusivity to which Plaintiffs and/or the '044 patent are, or become, entitled.

COUNT 7

(Infringement of U.S. Patent 8,679,069)

125. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

126. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '069 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '069 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '069 patent under 35 U.S.C. § 271(e)(2)(A).

127. On information and belief, Mylan was aware of the '069 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '069 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

128. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '069 patent, or any later date of exclusivity to which Plaintiffs and/or the '069 patent are, or become, entitled.

COUNT 8

(Infringement of U.S. Patent 8,992,486)

129. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

130. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '486 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '486

patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '486 patent under 35 U.S.C. § 271(e)(2)(A).

131. On information and belief, Mylan was aware of the '486 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '486 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

132. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '486 patent, or any later date of exclusivity to which Plaintiffs and/or the '486 patent are, or become, entitled.

COUNT 9

(Infringement of U.S. Patent 9,011,391)

133. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

134. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '391 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or

sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '391 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '391 patent under 35 U.S.C. § 271(e)(2)(A).

135. On information and belief, Mylan was aware of the '391 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '391 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

136. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '391 patent, or any later date of exclusivity to which Plaintiffs and/or the '391 patent are, or become, entitled.

COUNT 10

(Infringement of U.S. Patent 9,233,211)

137. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

138. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration

of the '211 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '211 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '211 patent under 35 U.S.C. § 271(e)(2)(A).

139. On information and belief, Mylan was aware of the '211 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '211 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

140. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '211 patent, or any later date of exclusivity to which Plaintiffs and/or the '211 patent are, or become, entitled.

COUNT 11

(Infringement of U.S. Patent 9,408,979)

141. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

142. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '979 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '979 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '979 patent under 35 U.S.C. § 271(e)(2)(A).

143. On information and belief, Mylan was aware of the '979 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '979 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

144. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '979 patent, or any later date of exclusivity to which Plaintiffs and/or the '979 patent are, or become, entitled.

COUNT 12

(Infringement of U.S. Patent 9,526,844)

145. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

146. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '844 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '844 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '844 patent under 35 U.S.C. § 271(e)(2)(A).

147. On information and belief, Mylan was aware of the '844 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '844 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

148. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the

expiration of the '844 patent, or any later date of exclusivity to which Plaintiffs and/or the '844 patent are, or become, entitled.

COUNT 13

(Infringement of U.S. Patent 9,533,105)

149. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

150. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '105 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '105 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '105 patent under 35 U.S.C. § 271(e)(2)(A).

151. On information and belief, Mylan was aware of the '105 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '105 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

152. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm

will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '105 patent, or any later date of exclusivity to which Plaintiffs and/or the '105 patent are, or become, entitled.

COUNT 14

(Infringement of U.S. Patent 9,561,331)

153. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

154. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '331 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '331 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '331 patent under 35 U.S.C. § 271(e)(2)(A).

155. On information and belief, Mylan was aware of the '331 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '331 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

156. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '331 patent, or any later date of exclusivity to which Plaintiffs and/or the '331 patent are, or become, entitled.

COUNT 15

(Infringement of U.S. Patent 9,604,008)

157. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

158. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '008 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '008 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '008 patent under 35 U.S.C. § 271(e)(2)(A).

159. On information and belief, Mylan was aware of the '008 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '008 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its

manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

160. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '008 patent, or any later date of exclusivity to which Plaintiffs and/or the '008 patent are, or become, entitled.

COUNT 16

(Infringement of U.S. Patent 9,604,009)

161. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

162. On information and belief, Mylan submitted NDA No. 210605 to obtain approval under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '009 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '009 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '009 patent under 35 U.S.C. § 271(e)(2)(A).

163. On information and belief, Mylan was aware of the '009 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '009 patent under 35 U.S.C. §§ 271(a), (b), and/or (c),

literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

164. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '009 patent, or any later date of exclusivity to which Plaintiffs and/or the '009 patent are, or become, entitled.

COUNT 17

(Infringement of U.S. Patent 9,610,409)

165. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

166. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '409 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '409 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '409 patent under 35 U.S.C. § 271(e)(2)(A).

167. On information and belief, Mylan was aware of the '409 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale

and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '409 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

168. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '409 patent, or any later date of exclusivity to which Plaintiffs and/or the '409 patent are, or become, entitled.

COUNT 18

(Infringement of U.S. Patent 9,623,189)

169. Plaintiffs repeat and re-allege paragraphs 1-100 above as if fully set forth herein.

170. On information and belief, Mylan submitted NDA No. 210605 to the FDA to obtain approval from the FDA under the FFDCA to engage in the commercial manufacture, use, importation, offer to sell and/or sale of its Proposed Prefilled Pen Product before the expiration of the '189 patent. On information and belief, Mylan filed NDA No. 210605 pursuant to § 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, and/or sale of the Proposed Prefilled Pen Product using data from bioavailability or bioequivalence studies conducted in connection with Sanofi's NDA No. 21-081 before the expiration of the '189 patent. Mylan's submission of NDA No. 210605 is an act of infringement of the '189 patent under 35 U.S.C. § 271(e)(2)(A).

171. On information and belief, Mylan was aware of the '189 patent prior to filing NDA No. 210605. If Mylan's NDA No. 210605 is approved, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of its Proposed Prefilled Pen Product would infringe the '189 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents because, *inter alia*, the Proposed Prefilled Pen Product constitutes a material part of the claimed invention and Mylan is aware that its manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product will constitute infringement.

172. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law. Such infringement and resulting irreparable harm will continue unless FDA's approval of NDA No. 210605 is stayed, and Mylan is enjoined by the Court from engaging in further infringing acts, pending a date that is not earlier than the expiration of the '189 patent, or any later date of exclusivity to which Plaintiffs and/or the '189 patent are, or become, entitled.

COUNT 19

(Declaratory Judgment of Infringement of U.S. Patent No. 7,476,652)

173. Plaintiffs repeat and re-allege paragraphs 1-104 above as if fully set forth herein.

174. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '652 patent.

175. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '652 patent before the expiration of the '652 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Products within the United States, or importation of

the Proposed Products into the United States, during the term of the '652 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '652 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

176. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

177. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Products prior to the expiration of the '652 patent would infringe the '652 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

178. Upon information and belief, Mylan has acted with full knowledge of the '652 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '652 patent.

179. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Products will constitute infringement of the '652 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 20

(Declaratory Judgment of Infringement of U.S. Patent No. 7,713,930)

180. Plaintiffs repeat and re-allege paragraphs 1-100 and 105-108 above as if fully set forth herein.

181. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '930 patent.

182. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '930 patent before the expiration of the '930 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Products within the United States, or importation of the Proposed Products into the United States, during the term of the '930 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '930 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

183. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

184. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Products prior to the expiration of the '930 patent would infringe the '930 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

185. Upon information and belief, Mylan has acted with full knowledge of the '930 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '930 patent.

186. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Products will constitute infringement of the '930 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 21

(Declaratory Judgment of Infringement of U.S. Patent No. 7,918,833)

187. Plaintiffs repeat and re-allege paragraphs 1-100 and 109-112 above as if fully set forth herein.

188. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '833 patent.

189. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '833 patent before the expiration of the '833 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '833 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '833 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

190. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

191. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '833 patent would infringe the '833 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

192. Upon information and belief, Mylan has acted with full knowledge of the '833 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '833 patent.

193. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '833 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 22

(Declaratory Judgment of Infringement of U.S. Patent No. 8,512,297)

194. Plaintiffs repeat and re-allege paragraphs 1-100 and 113-116 above as if fully set forth herein.

195. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '297 patent.

196. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '297 patent before the expiration of the '297 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '297 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '297 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

197. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

198. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '297 patent would infringe the '297 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

199. Upon information and belief, Mylan has acted with full knowledge of the '297 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '297 patent.

200. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '297 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 23

(Declaratory Judgment of Infringement of U.S. Patent No. 8,556,864)

201. Plaintiffs repeat and re-allege paragraphs 1-100 and 117-120 above as if fully set forth herein.

202. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '864 patent.

203. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '864 patent before the expiration of the '864 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use,

or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '864 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '864 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

204. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

205. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '864 patent would infringe the '864 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

206. Upon information and belief, Mylan has acted with full knowledge of the '864 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '864 patent.

207. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '864 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 24

(Declaratory Judgment of Infringement of U.S. Patent No. 8,603,044)

208. Plaintiffs repeat and re-allege paragraphs 1-100 and 121-124 above as if fully set forth herein.

209. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '044 patent.

210. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '044 patent before the expiration of the '044 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '044 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '044 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

211. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

212. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '044 patent would infringe the '044 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

213. Upon information and belief, Mylan has acted with full knowledge of the '044 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '044 patent.

214. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the

Proposed Prefilled Pen Product will constitute infringement of the '044 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 25

(Declaratory Judgment of Infringement of U.S. Patent No. 8,679,069)

215. Plaintiffs repeat and re-allege paragraphs 1-100 and 125-128 above as if fully set forth herein.

216. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '069 patent.

217. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '069 patent before the expiration of the '069 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '069 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '069 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

218. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

219. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '069 patent would infringe the '069 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

220. Upon information and belief, Mylan has acted with full knowledge of the '069 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '069 patent.

221. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '069 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 26

(Declaratory Judgment of Infringement of U.S. Patent No. 8,992,486)

222. Plaintiffs repeat and re-allege paragraphs 1-100 and 129-132 above as if fully set forth herein.

223. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '486 patent.

224. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '486 patent before the expiration of the '486 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '486 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '486 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

225. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

226. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '486 patent would infringe the '486 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

227. Upon information and belief, Mylan has acted with full knowledge of the '486 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '486 patent.

228. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '486 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 27

(Declaratory Judgment of Infringement of U.S. Patent No. 9,011,391)

229. Plaintiffs repeat and re-allege paragraphs 1-100 and 133-136 above as if fully set forth herein.

230. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '391 patent.

231. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '391 patent before the expiration of the '391 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use,

or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '391 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '391 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

232. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

233. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '391 patent would infringe the '391 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

234. Upon information and belief, Mylan has acted with full knowledge of the '391 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '391 patent.

235. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '391 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 28

(Declaratory Judgment of Infringement of U.S. Patent No. 9,233,211)

236. Plaintiffs repeat and re-allege paragraphs 1-100 and 137-140 above as if fully set forth herein.

237. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '211 patent.

238. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '211 patent before the expiration of the '211 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '211 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '211 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

239. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

240. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '211 patent would infringe the '211 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

241. Upon information and belief, Mylan has acted with full knowledge of the '211 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '211 patent.

242. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the

Proposed Prefilled Pen Product will constitute infringement of the '211 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 29

(Declaratory Judgment of Infringement of U.S. Patent No. 9,408,979)

243. Plaintiffs repeat and re-allege paragraphs 1-100 and 141-144 above as if fully set forth herein.

244. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '979 patent.

245. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '979 patent before the expiration of the '979 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '979 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '979 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

246. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

247. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '979 patent would infringe the '979 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

248. Upon information and belief, Mylan has acted with full knowledge of the '979 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '979 patent.

249. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '979 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 30

(Declaratory Judgment of Infringement of U.S. Patent No. 9,526,844)

250. Plaintiffs repeat and re-allege paragraphs 1-100 and 145-148 above as if fully set forth herein.

251. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '844 patent.

252. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '844 patent before the expiration of the '844 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '844 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '844 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

253. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

254. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '844 patent would infringe the '844 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

255. Upon information and belief, Mylan has acted with full knowledge of the '844 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '844 patent.

256. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '844 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 31

(Declaratory Judgment of Infringement of U.S. Patent No. 9,533,105)

257. Plaintiffs repeat and re-allege paragraphs 1-100 and 149-152 above as if fully set forth herein.

258. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '105 patent.

259. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '105 patent before the expiration of the '105 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use,

or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '105 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '105 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

260. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

261. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '105 patent would infringe the '105 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

262. Upon information and belief, Mylan has acted with full knowledge of the '105 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '105 patent.

263. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '105 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 32

(Declaratory Judgment of Infringement of U.S. Patent No. 9,561,331)

264. Plaintiffs repeat and re-allege paragraphs 1-100 and 153-156 above as if fully set forth herein.

265. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '331 patent.

266. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '331 patent before the expiration of the '331 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '331 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '331 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

267. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

268. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '331 patent would infringe the '331 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

269. Upon information and belief, Mylan has acted with full knowledge of the '331 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '331 patent.

270. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the

Proposed Prefilled Pen Product will constitute infringement of the '331 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 33

(Declaratory Judgment of Infringement of U.S. Patent No. 9,604,008)

271. Plaintiffs repeat and re-allege paragraphs 1-100 and 157-160 above as if fully set forth herein.

272. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '008 patent.

273. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '008 patent before the expiration of the '008 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '008 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '008 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

274. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

275. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '008 patent would infringe the '008 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

276. Upon information and belief, Mylan has acted with full knowledge of the '008 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '008 patent.

277. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '008 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 34

(Declaratory Judgment of Infringement of U.S. Patent No. 9,604,009)

278. Plaintiffs repeat and re-allege paragraphs 1-100 and 161-164 above as if fully set forth herein.

279. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '009 patent.

280. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '009 patent before the expiration of the '009 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '009 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '009 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

281. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

282. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '009 patent would infringe the '009 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

283. Upon information and belief, Mylan has acted with full knowledge of the '009 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '009 patent.

284. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '009 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 35

(Declaratory Judgment of Infringement of U.S. Patent No. 9,610,409)

285. Plaintiffs repeat and re-allege paragraphs 1-100 and 165-168 above as if fully set forth herein.

286. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '409 patent.

287. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '409 patent before the expiration of the '409 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use,

or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '409 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '409 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

288. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

289. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '409 patent would infringe the '409 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

290. Upon information and belief, Mylan has acted with full knowledge of the '409 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '409 patent.

291. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the Proposed Prefilled Pen Product will constitute infringement of the '409 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

COUNT 36

(Declaratory Judgment of Infringement of U.S. Patent No. 9,623,189)

292. Plaintiffs repeat and re-allege paragraphs 1-100 and 169-172 above as if fully set forth herein.

293. A definite and concrete, real and substantial judiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the '189 patent.

294. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States products patented by the '189 patent before the expiration of the '189 patent. If those substantial and meaningful preparations lead to Mylan's sale, offer for sale, use, or commercial manufacture of the Proposed Prefilled Pen Product within the United States, or importation of the Proposed Prefilled Pen Product into the United States, during the term of the '189 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '189 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

295. Mylan's actions, including but not limited to the filing of Mylan's NDA No. 210605, and Mylan's systematic attempt to meet the applicable regulatory requirements for approval of that NDA, indicate a refusal to change its course of action.

296. Upon information and belief, Mylan's manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States of the Proposed Prefilled Pen Product prior to the expiration of the '189 patent would infringe the '189 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

297. Upon information and belief, Mylan has acted with full knowledge of the '189 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '189 patent.

298. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of the

Proposed Prefilled Pen Product will constitute infringement of the '189 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or under the doctrine of equivalents.

PRAYER FOR RELIEF

Plaintiffs respectfully seek the following relief:

(a) The entry of judgment holding that Defendants have infringed each of the patents-in-suit;

(b) The entry of an order pursuant to 35 U.S.C. § 271(e)(4)(A), declaring that the effective date of any approval of Mylan's NDA No. 210605 shall be a date that is not earlier than the last date of expiration of any of the patents-in-suit and/or any additional period of exclusivity to which Plaintiffs and/or said patents are, or become, entitled;

(c) The entry of judgment declaring that the making, using, offering to sell, selling or importing of Proposed Products described in NDA No. 210605 would constitute infringement by Mylan of the patents-in-suit, or inducing or contributing to such conduct, pursuant to 35 U.S.C. § 271;

(d) The entry of a preliminary injunction, enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in concert with them, from infringing any of the patents-in-suit, from engaging in any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Proposed Products until after the expiration of the patents-in-suit (and any additional period of exclusivity to which Sanofi and/or the patents-in-suit are, or become, entitled), and from inducing or contributing to such activities;

(e) The entry of a permanent injunction enjoining Defendants, their officers, agents, attorneys, and employees, and those acting or attempting to act in active concert with them or acting on their behalf, from infringing any of the patents-in-suit by engaging in any

commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Proposed Products until after the expiration of the patents-in-suit (and any additional period of exclusivity to which Sanofi and/or the patents-in-suit are, or become, entitled), and from inducing or contributing to such activities;

(f) The entry of an order declaring that this is an exceptional case and awarding Plaintiffs their costs, expenses, and reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes, rules, and common law;

(g) The taxation of all allowable costs against Defendants; and

(h) The award to Plaintiffs of any other relief that the Court deems just and proper under the circumstances.

DATED: October 24, 2017

s/Liza M. Walsh

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RULE 11.2 CERTIFICATION

We hereby certify that, to the best of our knowledge, the matter in controversy is not the subject of any action pending in any court or of any arbitration or administrative proceeding, but it is related to the following actions:

Sanofi-Aventis U.S. LLC et al. v. Merck Sharp & Dohme Corp., Civil Action No. 1:16-cv-00812-RGA, pending in the United States District Court, District of Delaware before the Honorable Richard G. Andrews, U.S.D.J.;

Sanofi-Aventis U.S. LLC et al. v. Merck Sharp & Dohme Corp., Civil Action No. 2:17-cv-05914-SRC, pending in the United States District Court, District of New Jersey before the Honorable Stanley R. Chesler, U.S.D.J.;

Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH, Petition for Inter Partes Review as to Patent No. 7,476,652 filed on June 5, 2017 with the United States Patent and Trademark Office, Patent Trial and Appeal Board (IPR2017-01526); and

Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH, Petition for Inter Partes Review as to Patent No. 7,713,930 filed on June 5, 2017 with the United States Patent and Trademark Office, Patent Trial and Appeal Board (IPR2017-01528).

DATED: October 24, 2017

s/Liza M. Walsh

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RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

DATED: October 24, 2017

s/Liza M. Walsh
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